

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

## ***Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting***

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

October 17, 2011

### MEETING AGENDA

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*The committee will discuss supplemental new drug application (sNDA) 21641 (013) for AZILECT (rasagiline mesylate) Tablets, manufactured by Teva Neuroscience, Inc., for the following proposed indication: treatment of patients with idiopathic (of unknown cause) Parkinson's disease to slow clinical progression and treat the signs and symptoms of Parkinson's disease as initial monotherapy (the single drug used to treat) and as adjunct (additional) therapy to levodopa.*

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7:30 a.m.	Call to Order and Introduction of Committee	<b>Nathan Fountain, M.D.</b> Acting Chair, PCNS
7:40 a.m.	Conflict of Interest Statement	<b>Philip Bautista, Pharm.D.</b> Acting Designated Federal Officer, PCNS
7:45 a.m.	FDA Introductory Remarks	<b>Russell Katz, M.D.</b> Director Division of Neurology Products (DNP) Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
8:00 a.m.	<b>SPONSOR PRESENTATION</b>	<b>Teva Neuroscience, Inc.</b>
	Introduction	<b>Dennis Ahern, M.S.</b> Senior Director Regulatory Affairs Teva Neuroscience, Inc.
	Discussion of Medical Need	<b>C. Warren Olanow, M.D.</b> Mount Sinai School of Medicine
	TEMPO & ADAGIO Trials	<b>Cheryl Fitzer-Attas, Ph.D.</b> Director of Scientific and Medical Affairs Teva Neuroscience, Inc.
	Interpreting the Rasagiline Delayed-start Studies	<b>C. Warren Olanow, M.D.</b> Mount Sinai School of Medicine
	Conclusion	<b>Cheryl Fitzer-Attas, Ph.D.</b> Director of Scientific and Medical Affairs Teva Neuroscience, Inc.

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### MEETING AGENDA (*continued*)

9:30 a.m. Clarifying Questions

9:45 a.m. **BREAK**

10:00 a.m. **FDA PRESENTATION**

sNDA 21641 (013): Rasagiline Delayed Start  
Trials in Parkinson's Disease

**Tristan Massie, Ph.D.**  
Mathematical Statistician  
Division of Biostatistics I (DB-I)  
Office of Biostatistics (OB)  
Office of Translational Science (OTS)  
CDER, FDA

11:15 a.m. Clarifying Questions

11:30 a.m. **LUNCH**

12:30 p.m. Open Public Hearing Session

1:30 p.m. Questions to the Committee/Committee  
Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee  
Discussion

5:00 p.m. **ADJOURNMENT**